DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 18, 2015

B. Braun Medical Inc.
Mr. Gary Johnson
Manager, Regulatory Affairs
901 Marcon Boulevard
ALLENTOWN, PA 18109-9341

Re: K142596
Trade/Device Name: Infusomat® Space Volumetric Infusion Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 18, 2015
Received: May 20, 2015

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142596

Device Name
Infusomat® Space Volumetric Infusion Pump System

Indications for Use *(Describe)*
The Infusomat® Space Volumetric Infusion Pump System is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes include intravenous, intra-arterial, subcutaneous, and epidural.

The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

APPLICANT: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
Establishment Registration 2523676

Contact: Gary Johnson
Manager, Regulatory Affairs
Phone: 610-596-2263
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Email: gary.johnson@bbraun.com

DATE OF PREPARATION: June 18, 2015

DEVICE NAME: Infusomat® Space Volumetric Infusion Pump System

COMMON OR USUAL NAME: Infusion Pump

DEVICE CLASSIFICATION: Class II per 21 CFR §880.5725: Infusion Pump, Infusion Pump product code FRN

CLASSIFICATION PANEL: General Hospital

PREDICATE DEVICES: The Infusomat® Space Volumetric Infusion Pump System is comparable to and substantially equivalent to the Infusomat® Space Volumetric Infusion Pump System marketed under cleared 510(k) K083689.

The Alaris® Pump system by Care Fusion cleared under 510(k) K072105 is provided as a reference device for the new Autoprogramming feature. The Autoprogramming feature allows the pump to accept orders wirelessly from the facility's electronic health record (EHR) system. Although the pump can accept remote orders, it does not have the ability to start an infusion remotely.

DESCRIPTION:

The Infusomat® Space Volumetric Infusion Pump System includes an external, electronic infusion pump and pump accessories. The pump is transportable within a facility.

The Infusomat® Space pump utilizes a linear peristaltic pumping mechanism and is intended to provide infusions of parenteral fluids. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities. A trained Biomedical Technician must perform a complete set-up of the pump prior to use in a clinical setting.

The system is intended to provide intermittent or continuous flow of parenteral fluids to the patient. Parenteral fluids may include standard fluids and/or medications indicated for infusion as well as blood and blood products.
The Infusomat® Space is powered by an external power supply or by a rechargeable battery.
Infusomat® Space is capable of wireless communication both inbound and outbound.

SpaceStation with SpaceCom
The B. Braun Space Station is an 115V AC powered flexible docking and communication system for use in a medical facility. It is designed to accommodate multiple Infusomat® Space volumetric infusion pumps.

SpaceCom is a communication device that has been integrated into the SpaceStation. SpaceCom supports different interfaces such as Ethernet, PS2-Keyboard, Serial, USB ports and WLAN network card. Data transfer with the pumps is provided via an internal CAN bus. For barcoding, a barcode image reader can be connected to the PS2-Keyboard or USB interface. The pumps are coupled together with connectors on the inner backside of the SpaceStation. These connectors provide the voltage supply, distribute the information in the Space system via a serial interface, transfer data via a bus system (CAN bus) and transmit a staff call, which may be pending.

The outbound data communication through SpaceCom transfers status data of the infusion pumps to a hospital server and was cleared through the Infusomat Space Volumetric Infusion Pump System 510(k) K083689. The software in SpaceCom is being modified to allow inbound wired or wireless data communication to be uploaded. This includes data such as but not limited to drug libraries created by the DrugLibraryManager (DLM) to the infusion pumps.

Drug Library Manager and Drug Upload Manager

The Space OnlineSuite is a server based software system which provides the following applications:

Space Server Core

Space Server Core is the basic server framework for Space applications. This application framework provides basic server functions like User Management, License Management, Data Management, Communication Service, Security and Maintenance Functions. These functions are used by the administrator of the Space OnlineSuite. The applications, Drug Library manager and Upload Manager also use the basic functions of SpaceServer Core.

Drug Library Manager (DLM)

The Drug Library Manager allows the creation of unit and ward specific drug libraries and patient profiles. These features are designed to enhance medication safety and reduce medication errors.

Upload Manager (ULM)

The server-based Upload Manager can be used to manage the upload of drug libraries to any single B. Braun Space infusion pump, multiple Space pumps within a facility or to all Space pumps on the System. The drug libraries will be uploaded to SpaceCom residing in SpaceStation and then transferred via CAN bus (Controller Area Network) to the pumps or to a single Infusomat® Space Volumetric Infusion Pump directly.

INTENDED USE:

The Infusomat® Space Volumetric Infusion Pump System is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral fluids, medications, blood and blood products through clinically accepted routes of administration. These routes include intravenous, intra-arterial, subcutaneous, and epidural. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities.

The predicate device, the Infusomat® Space Volumetric Infusion Pump System (cleared in 510(k) K083689) is also intended for use on adults, pediatrics and neonates for infusion of parenteral fluids, medications, blood and blood products through FDA approved routes of administration. The patient population and infusion solutions are the same for the subject and predicate devices. The difference in the indication for the subject device is clarification of the routes of administration; intravenous, intra-arterial, subcutaneous and epidural. The routes of administration for the subject device are also FDA approved

routes of administration. Testing was conducted with the subject device to demonstrate that the differences in routes of administration do not affect the performance of the subject device. Both the subject and predicate devices are intended for prescription use as provided in the indications for use. Therefore, use by trained professionals in healthcare facilities was added to the indications for the subject device to provide further details. This does not affect the intended use since both the subject and predicate devices are intended for use by trained professionals in healthcare facilities.

SUBSTANTIAL EQUIVALENCE:

The subject device, the B. Braun Infusomat Space Volumetric Infusion Pump System is substantially equivalent to the Infusomat® Space Volumetric Infusion Pump System marketed under cleared 510(k) K083689. The intended use, operation and function of the subject device are similar to the identified predicate devices.

The similarities and differences between the subject device and predicate devices are identified in this submission. Performance testing conducted with the subject device demonstrates the device will function as intended. No new questions or issues of safety and effectiveness have been raised during verification and validation performed with the subject device.

Based on the information provided in this submission, the Infusomat Space Volumetric Infusion Pump System is substantially equivalent to the legally marketed predicate devices when used as instructed by trained healthcare professionals.

PERFORMANCE DATA NON–CLINICAL TESTING:

Performance data is provided for the subject device to support substantial equivalence. Non clinical testing was conducted with the subject device to demonstrate substantial equivalence to the predicate device. To verify that the subject device design is appropriate for the intended use and meets the user requirements, verification and validation testing were conducted. Test results demonstrate that the subject device functions as intended and is substantially equivalent to predicate device. Testing conducted included software and system verification and validation, delivery accuracy, usability, electromagnetic compatibility, functional and electrical safety. Human factors studies to validate the use safety and usability of the subject device were performed. The human factors studies were conducted with the intended user population, use

environment, and use scenarios to simulate clinical conditions of use. Results of the human factors testing demonstrate the device functions as intended under simulated conditions of use by the intended user population.

PERFORMANCE DATA
CLINICAL TESTING:

Clinical testing was not conducted with the subject device.

CONCLUSION: The nonclinical and simulated clinical use testing conducted using the subject device summarized above demonstrates that the subject device is substantially equivalent to the predicate device.